

SMALLPOX VACCINATION PROGRAM

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SMALLPOX VACCINATION SAFETY SUMMARY

DoD Smallpox Vaccination Program
Safety Summary, March 01, 2005

Background:

On December 13, 2002, the President directed smallpox vaccinations for selected military personnel, government workers, and contracted workers. DoD vaccinations began immediately for emergency response personnel and hospital staff members. Comprehensive training programs in vaccination technique, infection-control safeguards, screening and education methods, adverse event monitoring, and product storage and handling, aggressively launched in October 2002, made immediate vaccinations possible. In early January 2003, DoD began smallpox vaccinations of selected US military forces, and emergency-essential civilians and contractors deployed or deploying in support of U.S. Central Command missions.

Program Status:

DoD operational forces and healthcare workers vaccinated against smallpox: over 760,000. Detail about the DoD program appeared in the June 25, 2003 issue of the Journal of the American Medical Association (JAMA). The abstract of that article appears after the following summation of the program's current status:

In the 26.5 months between 13 Dec 02 and 01 Mar 05, the DoD administered more than 760,000 smallpox vaccinations. Most adverse events occurred at rates below historical rates.

- 92 cases of myo-pericarditis developed after smallpox vaccination. These cases have been followed carefully to evaluate their recovery, at over 30 hospitals in 25 States and several countries overseas. Detailed follow-up cardiac testing is available in 64 cases: all 64 had normal electrocardiograms (ECGs), echocardiograms ("echos"), and normal treadmill stress test results, suggesting a high rate of recovery. [See Journal of the American College of Cardiology. 2004 (Jul 7);44(1):201-5.]
- Another 16 cases of "ischemic" heart disease (such as heart attacks, atherosclerosis, or angina) occurred within 6 weeks after smallpox vaccination. This number of cases is similar to what normally occurs among unvaccinated military personnel of similar age.
- In no case was vaccinia (the live virus in the vaccine) transmitted from one person to another in the

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work place. Among 27,700 smallpox-vaccinated health-care workers, there were no cases of transmission of vaccinia from worker to patient.

- 53 cases (30 confirmed) of contact transfer of vaccinia virus have occurred, principally to spouses and adult intimate contacts. During education, we repeat the warning "Don't let your guard down at home."
- No cases of eczema vaccinatum or progressive vaccinia occurred. This indicates our education and exemption process is working well.
- The total number of treatments with vaccinia immune globulin (VIG) remains at three: one burn patient and two ocular patients.
- 43 cases of generalized vaccinia were treated, primarily as outpatients.
- Seven deaths due to disease after vaccination have been reviewed: one following an acute lupus-like illness may have been caused by vaccination, based on review by two independent panels of civilian physicians. Additional information on this case appears at www.vaccines.mil/panelreport.asp. The other deaths involved the following diagnoses (one each, except as noted): myocardial infarction, atherosclerotic coronary vascular disease (ASCVD, two), pulmonary embolism, heat injury, and benzodiazepine overdose. These deaths were judged unrelated to vaccination, based on individual factors such as preexisting disease, incidence among unvaccinated people, and lack of physical evidence to implicate a vaccine.

NOTE: All appropriate program information is provided regularly to federal health authorities, including all safety-surveillance data.

The June 25, 2003, issue of the Journal of the American Medical Association (JAMA) summarizes the DoD experience with smallpox vaccination to date. Below appears the abstract of this article:

US Military Smallpox Vaccination Program Experience John D. Grabenstein, RPh, PhD
William Winkenwerder, Jr., MD, MBA

Context. The United States recently implemented smallpox vaccination of selected military personnel in a national program of preparedness against use of smallpox as a biological weapon. The return of smallpox vaccinations raises important questions regarding implementation and safety.

Objective. To describe the US military smallpox vaccination program.

Design. Descriptive study of the vaccination program from its inception on December 13, 2002, through May 28, 2003.

Setting. US Department of Defense (DoD) fixed and field medical treatment facilities on multiple continents and ships at sea.

Subjects. US service members and DoD civilian workers eligible for smallpox vaccination.

Main Outcome Measures. Numbers of vaccinations and rates of vaccination exemptions, symptoms, and adverse events. Data was collected via reports to headquarters and rigorous surveillance for sentinel events.

Results. In 5.5 months, the DoD administered 450,293 smallpox vaccinations (70.5% primary vaccinees and 29.5% revaccinees). In 2 settings, 0.5% and 3.0% of vaccine recipients needed short-term sick leave. Most adverse events occurred at rates below historical rates. One case of encephalitis and 37 cases of acute myopericarditis developed after vaccination; all cases recovered. Among 19,461 worker-months of clinical contact, there were no cases of transmission of vaccinia from worker to patient, no cases of eczema vaccinatum or progressive vaccinia, and no attributed deaths.

Conclusions. Mass smallpox vaccinations can be conducted safely with very low rates of serious adverse events. Program implementation emphasized human factors: careful staff training, contraindication screening, recipient education, and attention to bandaging. Our experience suggests broad smallpox vaccination programs may be implemented with fewer serious adverse events than previously believed. JAMA. 2003;289:3278-3282 www.jama.com

Full article at: <http://jama.ama-assn.org/cgi/reprint/289/24/3278.pdf>

For more discussion of the myo-pericarditis cases, see: <http://jama.ama-assn.org/cgi/reprint/289/24/3283.pdf>

For the accompanying editorial, see: <http://jama.ama-assn.org/cgi/reprint/289/24/3306.pdf>

Perspective:

"Within DoD, we know a lot now about smallpox vaccine. We now have current, good experience with using it. The remarkable news about this program is that our adverse events do not reflect what history told us to expect. With proper care and attention, smallpox vaccine can be administered to large numbers of people safely. Those large numbers of vaccinated citizens discourage an enemy from using smallpox as a weapon."

- William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs

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